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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,129	04/10/2006	Deepak Murpani	RLL-320US	2714

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EXAMINER	
MERCIER, MELISSA S	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,129	MURPANI ET AL.	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7,9-13,16-27,45,46 and 49-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,7,9-13,16-27,45,46 and 49-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Applicants Remarks and Amended Claims filed on October 30, 2007 is acknowledged. Claims 1, 6-7, 9-13, 16-27, 45-46, and 49-51 are pending in this application. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-7, 9-13, 16-27, 45-46, and 49-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how many hydrophilic polymers applicant is claiming as required in the composition. The independent claims recite "one or more" and "wherein the hydrophilic polymers comprise a combination of cellulose ether and a carbohydrate gum". Therefore, it appears 2 polymers are required, not one.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 6-7, 9-13, 16-19, 21-24, 26-27, 45, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dilantin Physician Information Sheet in view of Vandecruys et al. (US Patent 6,667,060).

The Dilantin information sheet discloses 100mg Extended Release Oral Capsules, used as an antiepileptic drug, comprising 100mg phenytoin sodium, lactose monohydrate, sugar, talc and magnesium stearate. The capsules are made of gelatin and titanium dioxide. The product in vivo performance is characterized by a slow and extended rate of absorption with a peak blood concentration expected in 4-12 hours (see description). The product is supplied as hard, filled no. 3 capsules containing a white powder.

The Dilantin Information Sheet does not disclose a hydrophilic polymer is added to the phenytoin powder.

Vandecruys discloses a controlled release composition comprising hydrophilic controlled release matrix polymers (abstract). The hydrophilic polymers include

hydroxypropylmethylcellulose, hydroxypropylcellulose, and tragacanth, agar, guar, xanthan, for example (column 9, lines 1-58).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of the Dilantin Information Sheet with the teachings of Vandecruys polymers in order to provide a controlled pharmacokinetic release profile for a preparation. Vandecruys further discloses that depending on the amount of polymers used, the release profile can be tuned (column 9, lines 55-59).

Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

It is noted that Applicant is claiming a composition; therefore, the recitation of "wherein the powder blend has been screened through a mesh after blending but before filling in the capsules" is considered a process step, resulting in a product by process claim. The process step is therefore not given patentable weight when considering the product claim. It is further noted that it is the position of the examiner that it would have been obvious to a person of ordinary skill in the art to filter or pass the powder through a mesh prior to filling the capsules in order to obtain a uniform particle size for the powder.

Claims 1, 6-7, 9, 11-13, 17-19, 26-27 and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al. (US Patent 6,395,300).

Straub discloses a drug formulation comprising a low aqueous solubility drug provided in a porous matrix (abstract). Phenytoin sodium is disclosed as a suitable drug (column 5, line 44) and the drug matrix is in the form of powder (column 13, lines 29-31). Additionally, the matrices also may contain hydrophilic excipient such as water soluble polymers or sugars, wetting agents including acacia gum, surfactants, and tonicity agents" (Column 3, lines 50-53). Straub further teaches, "the porous drug matrix can be processed into capsules for oral administration" (column 3, lines 4-6).

Straub discloses the hydrophilic polymers can include "hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxyl-propylmethyl cellulose, and carboxymethyl cellulose" (column 8, lines 45-49).

Regarding Claim 6, "the porous drug matrix is at least 1-95% drug by weight" (column 3, lines 48-50).

Regarding Claim 7, Straub discloses, the amount of excipient in the drug matrix is less than 95% (column 8, lines 29-31). Straub defines excipient to include the hydrophilic polymers.

Regarding Claims 17-19, Straub discloses sugars such as "mannitol, dextrose and lactose" can be added to the drug matrix formulation (column 8, lines 58-65).

Regarding Claim 27, the selected drug is dissolved in an appropriate solvent; the drug solution is combined, typically under mixing conditions, with the pore forming agent

or solution thereof. A solid pore forming agent can be added directly to the drug solution as solid particulates, preferably between about 100 nm and 10 um in size, to form a suspension of pore forming agent in the drug solution. Subsequently, further processing the resulting suspension, for example, using homogenization or sonication techniques known in the art, can reduce the solid pore forming agent particle size. Then, the solution, emulsion, or suspension is further processed to remove the drug solvent and the pore forming agent simultaneously or sequentially, using evaporation, spray drying, fluid bed drying, lyophilization, vacuum drying, or a combination of these techniques. The solvent and pore forming agents evaporate from the droplets into the drying gas to solidify the droplets, simultaneously forming pores throughout the solid. The solid (typically in a powder, particulate form) then is separated from the drying gas and collected" (column 11, line 47 to column 12, line 41). Since Straub discloses the dosage form can be in the form of capsules, it is the examiners position that capsules would be filled with the above resulting powder.

It is noted that Applicant is claiming a composition; therefore, the recitation of "wherein the powder blend has been screened through a mesh after blending but before filling in the capsules" is considered a process step, resulting in a product by process claim. The process step is therefore not given patentable weight when considering the product claim. It is further noted that it is the position of the examiner that it would have been obvious to a person of ordinary skill in the art to filter or pass the powder through a mesh prior to filling the capsules in order to obtain a uniform particle size for the powder.

While it is noted that the prior art reference discloses phenytoin sodium among an extensive list of acceptable pharmaceutically active drugs, it is the position of the examiner that since it is specifically disclosed, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected it from the disclosed list.

Applicant is reminded that where the general conditions of the claims are met, burden is shitted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

Claims 20 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dilantin Physician Information Sheet in view of Vandecruys et al. (US Patent 6,667,060) and further in view of Sheth et al. (US Patent 4,588,589).

The combined teachings of the Dilantin Physician Information Sheet and Vandecruys are discussed above and applied in the same manner.

The use of microcrystalline cellulose and colloidal silicone dioxide are not disclosed.

Sheth discloses pharmaceutical dosage forms (abstract). Sheth further discloses compositions intended for oral use may be prepared according to methods known generally in the art. Such compositions may contain one or more agents selected from the group consisting of sweetening agents, flavoring agents, coloring agents and

preserving agents in order to provide a pharmaceutically elegant and palatable preparation. Orally, they may be administered in tablets, lozenges, oily suspensions, dispersible powders or granules, or hard or soft capsules which contain the active ingredients in admixture with non-toxic pharmaceutically acceptable excipient. Excipients which may be, for example, inert diluents, such as lactose, microcrystalline cellulose, starch, dextrose and mannitol; and lubricants, glidants, and anti-adherants, such as for example, silicone fluids, microfine silicas and talc (column 3, lines 1-39).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have substituted one excipient in a specific class for another art recognize functional equivalent. The disclosure of Sheath leads one of ordinary skill in the art to recognize microcrystalline cellulose is an art recognized equivalent of lactose and the same is true for silica and talc.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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